

Performance in Initiating Clinical Research - Quarter 2 (2019/20)

Note: Chelsea and Westminster Hospital NHS Foundation Trust formally acquired West Middlesex University Hospital NHS Foundation Trust on 01 September 2015 and the submission for the former West Middlesex University Hospital NHS Foundation Trust has been subsumed into

All clinical trials hosted between 1st October 2018 and 30th September 2019

Id	Research Ethics Committee Reference Number	Integrated Research Application System Number	Name of Trial	Date Site Invited	Date Site Selected	HRA Approval studies					Date of First Participant Recruited	Comments	Reasons for Delay correspond to
						HRA Approval Date	Date Site Confirmed By Sponsor	Date Site Confirmed	Date Site Ready To Start	Date Site Start			
151321	18/WA/0161	238902	An open-label, multi-centre, randomised, switch study to evaluate the virological efficacy over 96 weeks of 2-drug therapy with DTG+RPV FDC in antiretroviral treatment-experienced HIV-1 infected subjects virologically suppressed with NNRTIs resistance mutation K103N (WISARD)	10/09/2018	08/11/2018	04/10/2018	07/12/2018	18/12/2018	19/12/2018	12/03/2019	Site had a pool of potentially eligible patients whose medication was changed during set up resulting in them no longer being eligible.	NHS Provider	
151324	18/SW/0039	229163	The 'Big Baby Trial'	24/09/2018	23/11/2018	05/12/2018	28/11/2018	05/12/2018	07/12/2018	04/01/2019	None		
151325	18/LO/2068	254238	A multicenter, open-label, sponsor-blinded, randomized, active-controlled, parallel group, pivotal study to evaluate the efficacy, safety, and tolerability of murepavadin given with ertapenem versus an anti-pseudomonal 7-lactam-based antibiotic in adult subjects with nosocomial pneumonia suspected or confirmed to be due to Pseudomonas aeruginosa.	19/09/2018	12/11/2018						REC unfavourable opinion. Sponsor resubmitting to REC and HRA. No HRA Approval in place yet.	Sponsor	
151326	17/LO/2093	228763	A phase IV, open-label pilot study investigating non-invasive markers of hepatic fibrosis in people living with HIV-1 and non-alcoholic fatty liver disease randomised to receiving optimised background therapy (OBT) plus maraviroc or OBT	11/06/2018	14/02/2019	26/02/2018	18/02/2019	19/02/2019	20/02/2019	13/05/2019	None		
151327	16/WS/0057	193580	A randomised, open-label trial of a Multimodal Intervention (Exercise, Nutrition and Anti-inflammatory Medication) plus standard care versus standard care alone to prevent / attenuate cachexia in advanced cancer patients undergoing chemotherapy.	14/11/2018	07/02/2019	04/08/2016	12/04/2019	18/03/2019	12/04/2019	30/09/2019	Study difficult to recruit - rare patients	Neither	
151328	18/SC/0454	249509	Perioperative Ischemic Evaluation-3 Trial	05/02/2019	05/02/2019	16/01/2019	18/03/2019	22/03/2019	19/08/2019	17/09/2019	SIV delayed. Sponsor green light issued 19/08/19. Site had to recruit new staff to work on study.	Both	
151329	18/YH/0017	231431	Improving the safety and continuity of medicines management at care transitions	23/08/2018	11/01/2019	01/03/2018	11/01/2019	19/02/2019	03/04/2019	15/04/2019	None	Please Select...	
151330	18/LO/1537	227239	A single centre randomised controlled trial investigating the efficacy of The Zoo, a form of digital distraction as an analgesic and anxiolytic in the paediatric emergency department	23/04/2018	18/01/2019	18/01/2019	08/05/2019	08/05/2019	09/05/2019	10/05/2019	Research team amended protocol and CRF prior to green light causing delay in recruitment	Sponsor	
151331	18/LO/2033	252294	When to Induce Labour to Limit risk in pregnancy hypertension ? a multicentre, randomised controlled trial	13/02/2019	04/04/2019	10/01/2019	07/05/2019	07/05/2019	06/06/2019	08/08/2019	An initial cohort of potentially eligible patients was identified but following green light none were eligible due to developing pre-eclampsia	NHS Provider	
151332	18/LO/1352	243519	A Phase 3 Randomized, Placebo-Controlled, Double-Blind Study to Evaluate Upadacitinib in Adolescent and Adult Subjects with Moderate to Severe Atopic Dermatitis	07/09/2018	09/04/2019	03/01/2019	17/04/2019	17/04/2019	23/04/2019	05/06/2019	None		
151334	16/LO/1318	187932	Nucleos(t)ide withdrawal in HBsAg negative hepatitis B virus infection to promote HBsAg clearance. (NUC-B)	25/10/2018	12/04/2019	21/09/2016	07/05/2019	08/05/2019	14/05/2019		None		
151334	19/SC/0122	259342	A Randomized, Double-Blind, Placebo-Controlled Study of Diazoxide Choline Controlled-Release Tablet (DCCR) in Patients with Prader-Willi Syndrome	25/10/2018	08/05/2019	07/05/2019	23/05/2019	23/05/2019	04/06/2019	10/07/2019	None		
151335	19/LO/0400	250289	The Impact of using FilmArray Pneumonia Panel Molecular Diagnostics for Hospital-Acquired and Ventilator-Associated Pneumonia on Antimicrobial Stewardship and Patient Outcomes in UK Critical Care: A Multicentre Randomized Controlled Trial.	01/04/2019	02/06/2019	09/04/2019	01/07/2019	02/07/2019	04/07/2019	30/07/2019	None		
151336	17/LO/0621	191390	Standard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AK): A Multi-Centre Randomized Controlled Trial	16/11/2018	03/06/2019	22/05/2017	18/06/2019	19/06/2019	05/07/2019		None		
151337	19/LO/0666	261913	Pharmacokinetics of plasma doravirine once daily over 72 hours following drug intake cessation in healthy volunteers	01/01/2019	10/06/2019	10/06/2019	10/06/2019	10/06/2019	12/06/2019	25/06/2019	None		
151338	18/WM/0352	241385	An Open-Label, Multi-Centre, Randomised Study to Investigate Integrase Inhibitor Versus Boosted Protease Inhibitor Antiretroviral Therapy for Patients with Advanced HIV Disease. The Late Presenter Treatment Optimisation Study (LAPTOP).	21/01/2019	21/03/2019	15/01/2019	08/04/2019	18/04/2019	09/05/2019	21/06/2019	Site target just 2 patients - study very difficult to recruit to.	Both	
153030	19/LO/0905	257865	PIBIK Study	02/05/2019	05/08/2019	17/07/2019	21/08/2019	10/09/2019	25/09/2019		None		
153031	19/EE/0185	260536	FIRST-line support for Assistance in Breathing in Children (FIRST-ABC)	04/06/2019	07/08/2019	26/07/2019	04/09/2019	06/09/2019	09/09/2019	16/09/2019	None		
153032	19/NS/0162	264547	SMOKEFREE	28/08/2019	28/08/2019						None		
153033	19/LO/0040	253233	Apremilast Phase4 Study on Quality of life in psoriasis manifestations	27/03/2019	29/08/2019	19/02/2019	12/09/2019	17/09/2019	18/09/2019		None		
153034	19/LO/1043	261870	Ertugliflozin versus Placebo in Paediatric Type 2 Diabetes	19/06/2019	07/09/2019	07/10/2019	26/09/2019	02/10/2019			None		
153035	17/EE/0347	201505	IASO	12/09/2019	12/09/2019	17/10/2017	11/10/2019	15/10/2019			None		
153036	18/EM/0310	239782	C-STICH2 Randomised controlled trial of emergency cerclage	09/05/2019	12/09/2019	16/11/2018					None		
153037	19/LO/0452	250324	CASTLE TRIAL v1.0	29/07/2019	13/09/2019	02/05/2019	01/10/2019	25/09/2019			None		
153038	19/WA/0005	246081	IP2 - ATLANTA	17/09/2019	24/09/2019	14/03/2019	21/10/2019	17/10/2019	21/10/2019		None		